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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,946	04/11/2005	Motohiro Ohta	03299.000001.	8311

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EXAMINER	
WELTER, RACHAEL E	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,946	OHTA ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,8,10,12 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,8,10,12 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 2-3, 8, 10, 12, and 18-21 are pending. Claims 1, 4-7, 9, 11, and 13-17 are cancelled.

Acknowledgements

Receipt of the amendment and supplemental amendment and remarks/arguments filed on 11/18/08 and 12/16/08 is acknowledged respectively.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. No English translation of the Certified Copy of the Foreign Priority Application has been received. Thus, priority will not be granted unless the English translation of the priority document is received.

Double Patenting

The terminal disclaimer filed on 11/18/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application No. 10/250,863 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The rejection of claims 1 and 13-15 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, 9 of copending Application No. 10/546,439 in view of Alkire et al (US Patent No.

5,607,697), Murakami et al (US Patent No. 6,287,596) and Tiwari et al (*AAPS Pharmsci* 1999; 1(3) article 13) is withdrawn in light of applicant's amendment.

New Rejections

The following rejection constitutes new grounds for rejection necessitated by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 1, 3-4, 13, & 15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendment.

However, the following additional rejections under 35 U.S.C. 112, second paragraph are made in light of applicant's amendment:

Claims 3, 8, 10, and 12, and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3 and its dependent claims, claim 3 recites the limitation "which comprises at least one of sodium starch glycolate or calcium carboxymethylcellulose." There is insufficient antecedent basis for this limitation in the claim because the claim is

dependent on claim 2, which does not recite or have support for sodium starch glycolate or calcium carboxymethylcellulose. In order to overcome this rejection, applicant should amend the claim to recite, "...which further comprises at least one of sodium starch glycolate or calcium carboxymethylcellulose."

Regarding claim 12, wherein the amino acid is a mixture of a pure amino acid and a proteolytic mixture, the claim is indefinite because it is dependent on claim 1, which comprises an amino acid consisting of valine, leucine, and isoleucine. Thus, the transitional language of claim 1 excludes any element, step, or ingredient not specified in the claim. More specifically, the amino acid can only consist of three branched amino acids. However, claim 12 recites that the amino acid can also comprise a proteolytic mixture. Thus, the claim 12 is indefinite because the examiner cannot determine if applicant means to claim an amino acid consisting of just valine, leucine and isoleucine or an amino acid comprising of valine, leucine, isoleucine, and a proteolytic mixture. Claims 20 and 21are rejected as being dependent from claim 12 even though they further define the amount of amino acid. For examination purposes, the examiner will examine an amino acid consisting of valine, leucine, and iosleucine as recited in instant claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2, 8, 10, 12, and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 2001-258509 (Translation provided herein) as evidenced by Alkire et al (US Patent No. 5,607,697).

JP '509 discloses a tablet containing amino acid and a RAKUCHI torr (which translates to lactitol). In examples 1-4, the branched amino acids: valine, leucine, and isoleucine are granulated into a tablet (paragraphs 0016-0022). The total amino acid content is 40 wt.% in the working examples (The first three ingredients of tables 1, 2, and 4). JP '509 discloses that the hardness of the tablet can be 6.0 kg, 6.2 kg, 6.5 kg, etc in table 3, which corresponds to 60, 62, and 65 N (paragraph 0021).

Although JP '509 is silent regarding the tablet being an intraorally rapidly disintegrable chewable table wherein the time until one tablet is disintegrated by saliva alone after chewing in the oral cavity of a healthy adult is 60 to 150 seconds, it is the position of the examiner that this is an expected property of the tablet. Since the prior art anticipates all the structural limitations of the tablet in the instant claims, the examiner has no reason to believe that JP '509 is not disclosing an intraorally rapidly disintegratable chewable tablet. In addition, Alkire et al provide evidence that the tablet is an intraorally rapidly disintegratable chewable tablet because Alkire et al teach solid dosage forms with cores comprising sugar alcohol, which can be orally disintegratable (abstract; column 9, lines 55-67). Furthermore, Alkire et al teach that the active agent in the tablet can be amino-acids comprised between about 0.1-67% by weight of the finished dosage form (column 5, line 34; column 6, lines 6-9). According to MPEP

2112.02, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)*. In addition, since the examiner has no access to laboratory equipment, burden is shifted to applicant to prove otherwise as *In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001-258509 (Translation provided herein) as evidenced by Alkire et al (US Patent No.

5,607,697) as applied to claims 2, 8, 10, 12, and 18-21 above and in further view of Creekmore et al (US Patent No. 6,316,640).

The disclosure of JP '509 is discussed above.

JP '509 does not teach a tablet further comprising at least one of sodium glycolate or calcium carboxymethylcellulose. However, JP '509 does teach tablets comprising crystalline cellulose (paragraph 0016).

Creekmore et al teach pharmaceutical formulations, such as tablets comprising disintegrants chosen from croscarmellose sodium, crospovidone, polyvinylpyrrolidone, sodium starch glycolate, corn starch, microcrystalline cellulose, hydroxypropyl methylcellulose and hydroxypropyl cellulose (column 2, lines 16-17; column 2, lines 39-42).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to combine the teachings above and utilize the disintegrants of JP '509 or Creekmore et al. One would have been motivated to do so since Creekmore et al teach that the instant disintegrant and JP '509's disintegrant (crystalline cellulose) are both suitable disintegrants used in tablets. Thus, one would have been motivated to substitute the instant disintegrant (sodium starch glycolate) into the tablet of JP '509 with an expectation of similar results since Creekmore et al teach the equivalency of the disintegrants.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection above. The examiner notes that Alkire et al (US Patent No. 5,607,697) was used in the previous rejection mailed on 5/23/08 but notes that it is only cited in the new rejections for the purpose of providing evidence.

Conclusion

Claims 2-3, 8, 10, 12, and 18-21 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
March 29, 2009